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510(k) Summary
for the OsteoSpring FootJack™ Subtalar Implant System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the OsteoSpring FootJack™ Subtalar Implant System.

1. GENERAL INFORMATION

Date Prepared: September 7, 2011

Trade Name: OsteoSpring FootJack™ Subtalar Implant System

Common Name: Subtalar implant

Classification Name: Screw, fixation, bone

Class: II

Product Code: HWC

CFR section: 21 CFR section 888.3040

Device panel: Orthopedic

Legally Marketed Predicate Devices: OsteoMed Subtalar Implant System - K031155
Instratek Subtalar Lok™ - K080280
BioArch™ Subtalar Implant - K070441

Submitter: OsteoSpring Medical Inc.
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2. DEVICE DESCRIPTION

The OsteoSpring FootJack™ subtalar implant is intended to be implanted into the sinus tarsi of the foot. It will be available in a range of sizes. The implant is a solid, one-piece, conical, thread shaped and cannulated design.

Materials:
Titanium Alloy ELI per ASTM F136.

Function:
The conical threaded design of the FootJack implant is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but limiting excessive pronation and resulting sequela.

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The OsteoSpring FootJack™ subtalar implant is substantially equivalent to the OsteoMed Subtalar Implant System, Instratek Subtalar Lok™ and BioArch™ Subtalar Implant in terms of intended use, design, materials used, mechanical safety and performances.

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4. **INTENDED USE**

The OsteoSpring FootJack™ Subtalar Implant System is indicated for use in the treatment of hyperpronated foot and stabilization of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but limited excessive pronation and resulting sequela. The OsteoSpring FootJack Implant System implants are intended for single patient use only.

5. **NON-CLINICAL TEST SUMMARY**

The following tests were conducted:

- Finite Element Analysis
- Static compression testing

The results of this testing indicate that the OsteoSpring FootJack™ Subtalar Implant met the acceptance criteria and withstood the load testing without functional failure or defect.

6. **CLINICAL TEST SUMMARY**

No clinical studies were performed.

7. **CONCLUSIONS NONCLINICAL AND CLINICAL**

The OsteoSpring FootJack™ Subtalar Implant System is substantially equivalent to the predicate devices in terms of indications for use, design, material, performance and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OsteoSpring Medical, Inc.
% The OrthoMedix Group, Inc.
% Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

DEC 12 2011

Re: K112658
Trade/Device Name: OsteoSpring FootJack Subtalar Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: September 7, 2011
Received: September 13, 2011

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112658

Device Name: OsteoSpring FootJack™ Subtalar Implant System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112658